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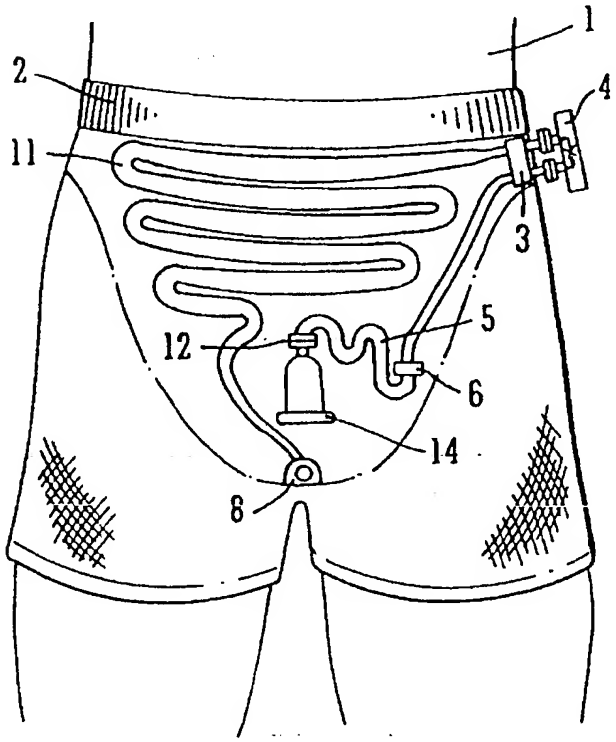
(54) Title: AN INCONTINENCE APPLIANCE

(57) Abstract

An incontinence appliance comprising a pair of briefs (2) to be worn by the user and incorporating a reservoir (11) distributed about the front of the briefs (2) thus to be worn over the user's abdominal region. The reservoir (11) forms a temporary containment for urine and is filled via a feed tube (5) connected to the urethra, and a pump (4) to direct the urine steadily into the reservoir (11) which, when filled, may be voided by an outlet aperture (8). A warning device is provided to advise the user when the reservoir (11) is approaching a full condition.



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AN INCONTINENCE APPLIANCE

Urinary incontinence is a condition which restricts the normal activity of patients both physically and psychologically. Two conventional methods of dealing with urinary incontinence are catheterisation with collection of urine in a plastics bag, and the use of absorbent pads.

Physical restrictions are imposed upon patients who are catheterised and collect urine into leg-mounted bags, or who have to use bulky absorbent pads. These conventional methods of handling uncontrolled urine production lead not only to restriction of activities such as walking, shopping, cycling etc., but also impact psychologically on the patient's confidence, mainly through fear,imagined or real, of unpleasant odours arising from the use of such methods.

The system according to the present invention frees the incontinent patient from these physical and psychological restrictions thus ensuring a comfortable and greatly improved quality of life. The system also provides benefits to medical and nursing staff who have to look after incontinent patients.

Thus the present invention provides an artificial urine collection system which allows renewed control of urinary incontinence by the user.

Embodiments of the invention will now be described by

way of example, with reference to the accompanying drawings in which:-

Figure 1 shows, in front view, a first embodiment being an appliance for male incontinence patients;

Figure 2 shows, in front view, a second embodiment being an appliance for male incontinence patients;

Figure 3 shows, in front view, a third embodiment being an appliance for female incontinence patients;

Figure 4 shows, in front view, a fourth embodiment being an appliance for female incontinence patients;

Figure 5 is a side view of the appliance of Fig. 1;

Figure 6 is a side view of the appliance of Fig. 3.

Figure 7 shows a pump including a quick-fitting snap-on connection of the pump to a urine collecting system;

Figure 8 shows a pump control mechanism.

Figures 9 to 12 show, in front view, various alternative forms of urine collecting reservoir forming part of the appliance; and

Figure 13 is a schematic illustration of an appliance with flow monitoring and warning devices.

An incontinence appliance made in accordance with the invention and adapted for male or female use will now be described with Figures 1, 2 and 5 relating to a male appliance and Figures 2, 3 and 6, to a female appliance. Figures 7 to 13 are common to both forms of appliance.

The wearer's abdominal region is illustrated at 1 and the appliance is attached to and/or incorporated within a pair of briefs 2 to be worn in place of the usual underwear.

Included within the briefs 2 is a reservoir for the temporary containment of urine, which in this example is illustrated as a length 11 of lay-flat tubing of a material impervious to liquid, for example, plastics, connected at one end to a miniaturised electric pump 4 and at the other end to a normally closed drainage outlet 8.

The pump 4 draws urine from a sheath 14 (for male patients) via a feed tube 5 having a control valve 6 whereby urine voided from the patient's bladder is taken into the system from the sheath 14 via the valve 6 and pump 4 into the reservoir 11.

By providing the reservoir in the form of lay-flat tubing, this gradually fills over a period of time, and once completely filled or almost approaching that condition the reservoir may be voided selectively by the patient via the drainage outlet 8. As the reservoir tubing 11 is deployed over the abdominal region of the patient the existence of urine contained therein is concealed and worn more comfortably when compared with a conventional bag and leg strap.

Although not illustrated and described in detail with reference to Fig. 1, a system is provided whereby the patient is made aware when the reservoir 11 is approaching a filled condition. This

could be an electronic device sensing the level or quantity of urine collected, or a tactile device to make the patient aware of the ensuing condition.

Referring now to Fig. 2 , certain patients may need to be catheterised and so a catheter 13 is illustrated as replacing the sheath 14 of Fig. 1. Fig. 5 illustrates in side view or vertical section how the various parts of the appliance are distributed over the height of the briefs to accommodate as compactly as possible, the various parts of the system.

Referring now to Fig. 3, in an embodiment for female patients the feed tube carrying urine via the pump 4 to the reservoir 11 is connected to the patient via a device 15 and a one-way valve 12. Otherwise, the parts of the system may be identical to those in the appliance for male patients.

An incontinence control system as described serves as an external artificial bladder allowing the collection of urine from the incontinent patient in a comfortable, dignified and controlled way. When urine is produced at the exit point of the urethra it is drawn along the tube 5 by the pump 4 and allowed to collect in the ribbon of lay-flat tubing sewn into the front panel of the briefs 2 such that the weight of the collected urine is evenly distributed over the front of the undergarment. This system allows for several hours of urine production without any noticeable weight change by the user because the area of distribution is large. The system automatically informs the patient when the artificial bladder is approaching maximum

capacity and enables the patient to decide when and where to void the urine. The act of voiding the bladder can be actively or passively performed.

The system is simple to use and easy to operate. The first stage involves fitting the appropriate anchoring system to the individual's body. This will be either an external device (14, 15) or a fitted catheter with connector. Once the appropriate anchor is in place, the special briefs, incorporating the external bladder system, are put on and connected at the anchor snap-on connector 12 using a connection system 3. The pump is switched on and the system is ready for use.

Referring now to Figs. 7 and 8, a snap-on, quick-fitting connection 3 enables connection of the pump 4 to the tube 5 and reservoir 11 with ports 3a provided on the pump body for this purpose. A clip 4a enables the pump to be attached removably to the waistband of the briefs 2.

Figure 8 shows (at 8a) how urine may flow through the valve/connector 6 in normal use, and (at 8b) how the wall of the tube 5 is caused to collapse by suction from the pump when no urine is flowing from the patient. The resultant increased electrical current drawn by the motor 4 when the tube is collapsed as illustrated at 8b may be detected by an electronic control mechanism to cause the motor to shut down. After a predetermined time delay the pump would restart.

In one example, a system whereby the patient will be notified when the reservoir approaches a full condition includes an electrically resistive strip attached to the outer surface of the lay-flat tubing forming the reservoir 11. In this case, as the tubing swells due to the presence therein of the urine the resistive strip is caused to stretch and the change in electrical resistance created thereby may be used electronically to trigger a preset alarm or warning device to indicate a full condition. Therefore, this would replicate the physiological sensation created during normal bladder functions. It will be appreciated that the gradually expandable nature of the reservoir 11 eliminates potentially embarrassing noise which might be audible with use of a conventional fixed-volume vessel.

The alarm signal produced by the warning device may be audible or tactile. In a simple form of the device urine may be voided from the reservoir 11 by the user manually operating a valve allowing the collected urine to be transferred into a bag which may then be disposed of conveniently and hygienically.

The pump 4 and warning device may be powered by a battery worn about the person and electronically associated with a battery-low alarm whereby the patient is assured that the system is working properly.

As an alternative form of warning device there may be provided a flow meter which detects and records a volumetric quantity or urine passing into the reservoir. Thus, at a predetermined

quantity a warning system may be transmitted. One example of a tactile warning system would be small pair of positive and negative electro-pads in contact with the body and adapted to send signals via the patient's nervous system. These signals would continue and may increase in intensity as the reservoir approaches a full condition such that the patient may void the reservoir at the earliest convenient opportunity.

Figures 9 to 12 illustrate various forms of external reservoir which may replace the lay-flat tubing 11. Each of these alternative reservoirs may be designed to fit over or under the front of the briefs 2 in much the same manner as the lay-flat tubing illustrated previously. For example, a strip 21 of touch-and-close fastener may be used or alternatively a button and button hole assembly as illustrated at 22. An input tube 33 having a non-return valve 44 is provided in the upper region of the reservoir for the inflow thereto of urine from the pump.

In Fig. 9 the reservoir consists of an upper chamber 25 having several vertical ducts 28 extending downwardly therefrom, each in communication with a series of miniature bubble compartments 29. The chamber 25, ducts 28 and compartments 29 are all in communication with each other and with a voiding or drainage duct 30 having a shut-off control valve 27.

In Fig. 10 the reservoir differs in that the individual bubble compartments are not connected laterally and all drain into a

common lower chamber 31.

In Figure 11 the reservoir is similar to reservoir 11 in the previous examples except that in place of the continuous lay-flat tubing there is provided a continuous series of in-line bubble compartments 35 in a common and continuous tube 36 which extends from the inlet tubing 33 down into the outlet duct 30. Figure 12 illustrates the alternative use of an upper chamber 35 which communicates with a large central vertical duct 36 and a lower chamber 38 which gradually fills occupying spaces 39 divided by collection baffles 40 which prevent the collected urine from lateral and vertical movement.

The various collection reservoirs illustrated in Figs. 9 to 12 are examples only of many variations in design which may be adopted for the purpose of evenly distributing the weight and volume of urine collected in the reservoir and to prevent excessive free movement of the liquid within the reservoir as the patient moves about during normal activity. The materials used for the construction of the reservoir may be of natural or synthetic rubbers or plastics and can be produced in a range of sizes as appropriate for the particular patient.

Figure 13 illustrates in further detail certain parts of the appliance according to one example and including a pump housing 50 which may, for example, be removably clipped onto the waistband of the briefs 2 illustrated in the earlier examples. Contained within the housing 50 is the pump 4 and a volumetric flow meter 51 adapted to

detect the volume of urine flowing through the pump. A rechargeable battery 52 is also contained within the housing 50 with terminals 53 exposed for recharging the battery. Inlet and outlet port 54 and 55 respectively are attached to feed tube 5 and reservoir 11.

A pair of tactile pads 56 is electrically connected to circuitry within the housing 50 to receive therefrom a signal when the reservoir 11 is approaching a full condition, the pads being arranged for physical contact with the wearer's skin, for example, by mounting on the rear face of the reservoir 11.

LED indicator lights 57 and 58 and a battery-low indicator 59 may be provided on the housing 50 if required.

Dedicated electronic circuitry contained within the housing 50, details of which would be readily understood by a person skilled in the art, is adapted to receive signals from the flow meter 51 and to transmit resultant signals to the tactile pads 56 and/or the indicators 57 and 58 to provide a tactile and/or visual warning to the wearer when a certain quantity or volume of urine has flowed through the pump into the reservoir 11. Thus the wearer is advised when the reservoir is approaching a full condition and requires to be voided. In place of pads 56 and indicators 57, 48, a signal may be transmitted to, for example, an audible device or a device similar to a pager.

The feed tube 5 may also contain a moisture sensor 60 electrically connected to the internal circuitry and adapted to control

2, including a pump connectable via a feed tube to the user's urethra, and to the reservoir for directing urine from the urethra into the reservoir.

8. An incontinence appliance according to Claim 7, wherein said pump is electrically motor driven.

9. An incontinence appliance according to Claim 7, wherein the pump is an electro-magnetic pump.

10. An incontinence appliance according to Claim 7, including a rechartable battery for driving the motor.

11. An incontinence appliance according to Claim 7, including a moisture sensor adapted to control operation of the pump.

12. An incontinence appliance according to Claim 2, wherein said warning device includes a volumetric flow meter adapted to sense the quantity of urine flowing into the reservoir and to provide an electrical signal to be transmitted to the warning device.

13. An incontinence appliance according to Claim 1, wherein the reservoir includes an upper chamber having one or more vertical ducts extending therefrom each in communication with a series of bubble compartments, all in communication with a drainage duct.

14. An incontinence appliance according to Claim 13, wherein the reservoir includes a common lower chamber to receive

urine separately from said bubble compartments.

15. An incontinence appliance according to Claim 1, wherein the reservoir comprises a continuous tube communicating with a plurality of in-line bubble compartments.

16. An incontinence appliance according to Claim 2, including electronic circuitry including means to control operation of the pump and the full-condition warning means.

17. An incontinence appliance according to Claim 1, including means to enable a sample of urine to be extracted from a part of the appliance.

18. An incontinence appliance according to any preceding claim, wherein the reservoir is provided as a component removable from the remainder of the appliance.

19. An incontinence appliance according to Claim 1, wherein the means for removably connecting the reservoir to the user's urethra is an external anchor.

20. An incontinence appliance according to Claim 1, wherein the means for removably connecting the reservoir to the user's urethra is a catheter.

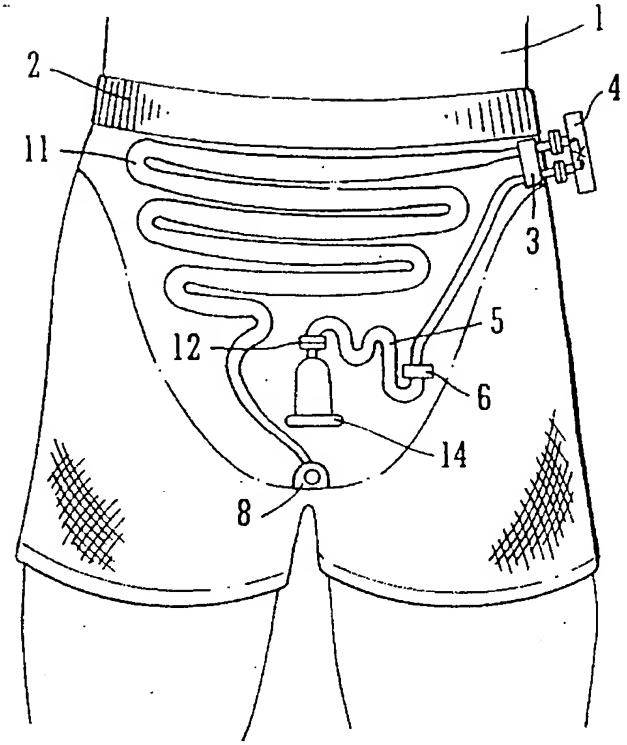

FIG. 1

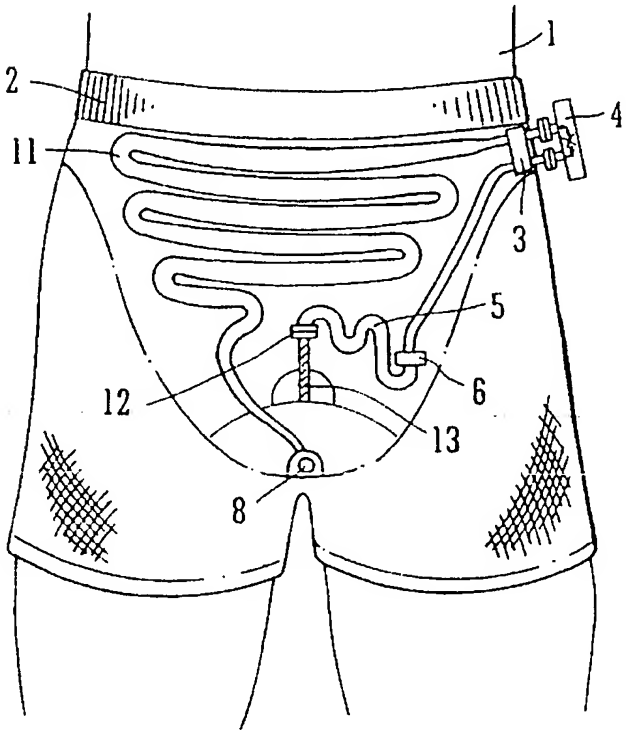

FIG. 2

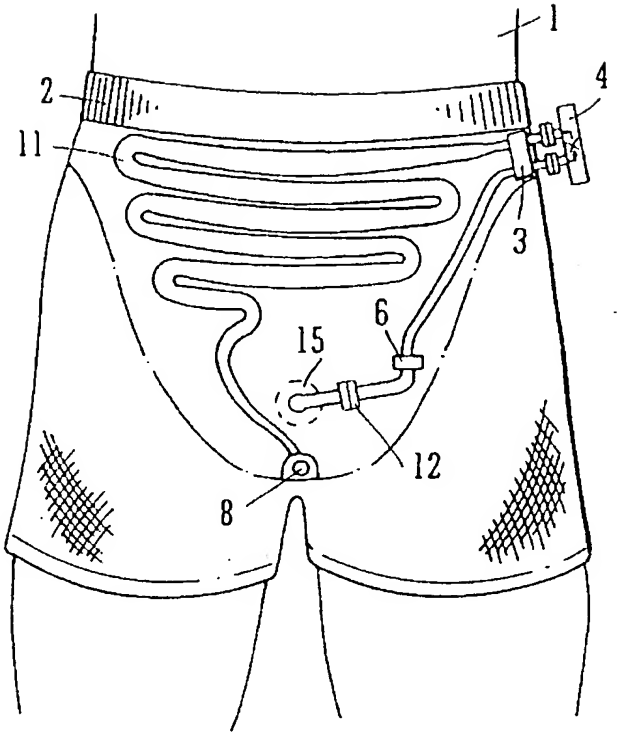

FIG. 3

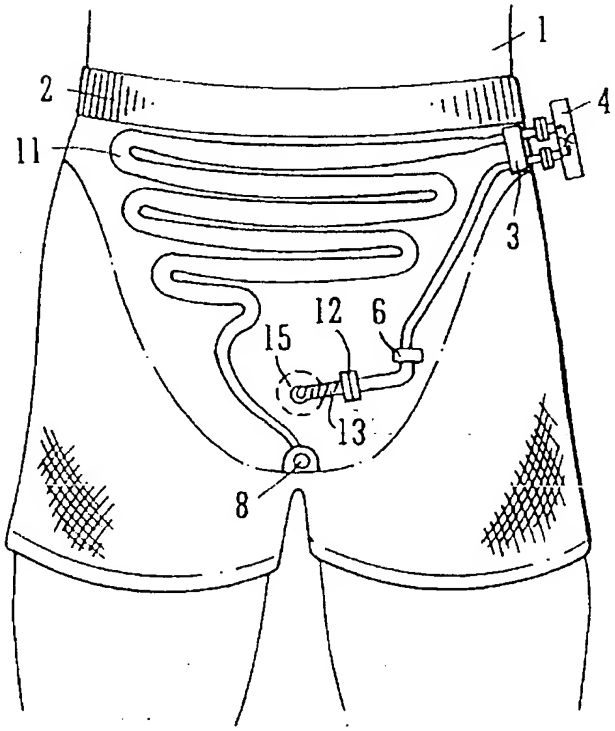

FIG. 4

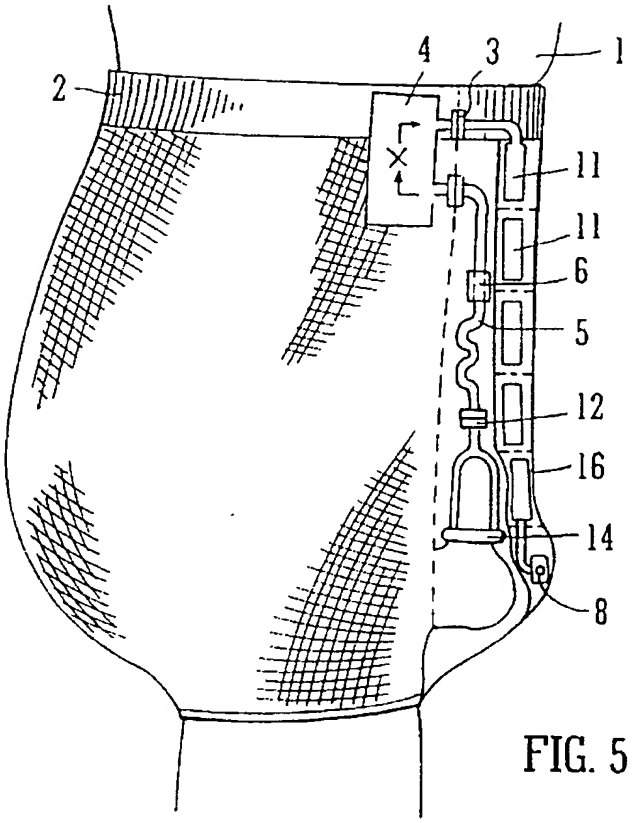

FIG. 5

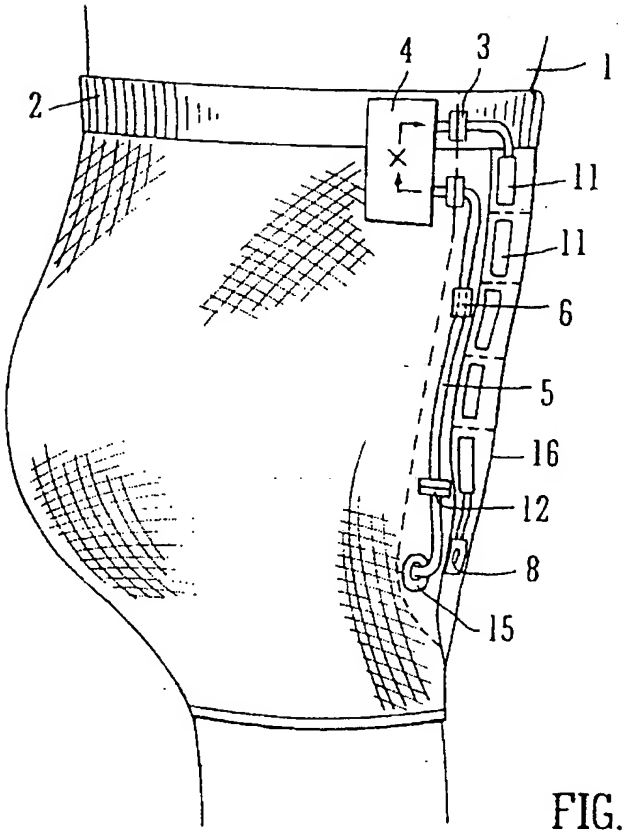

FIG. 6

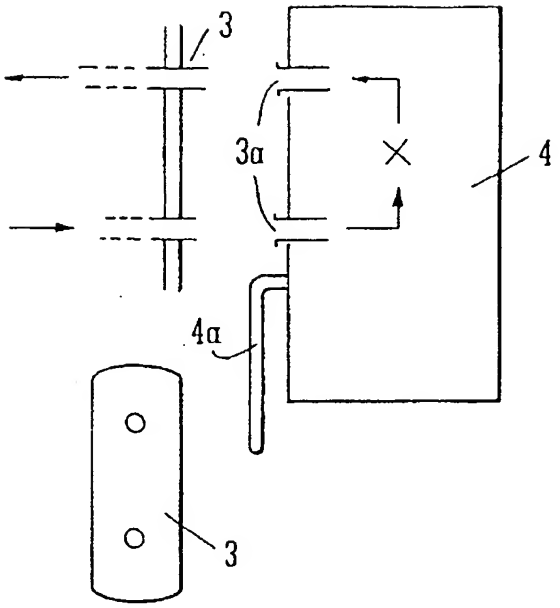

FIG. 7

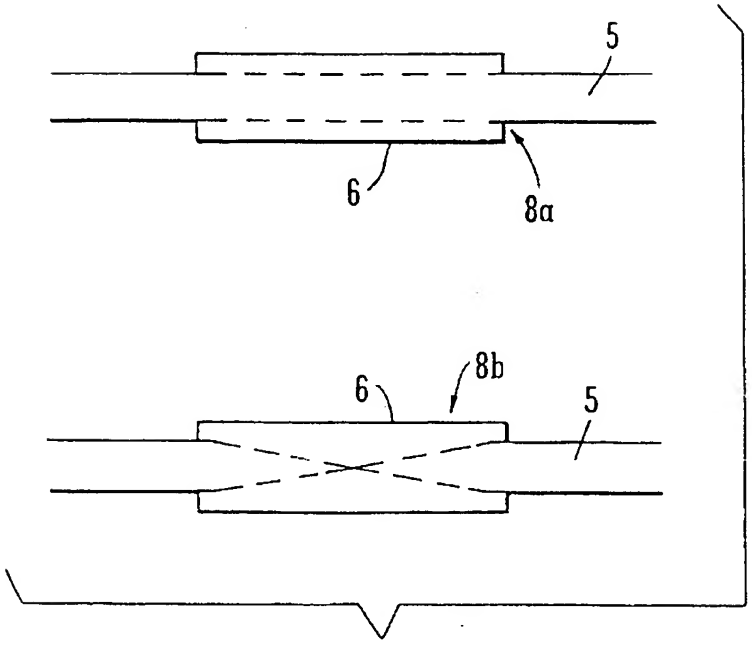

FIG. 8

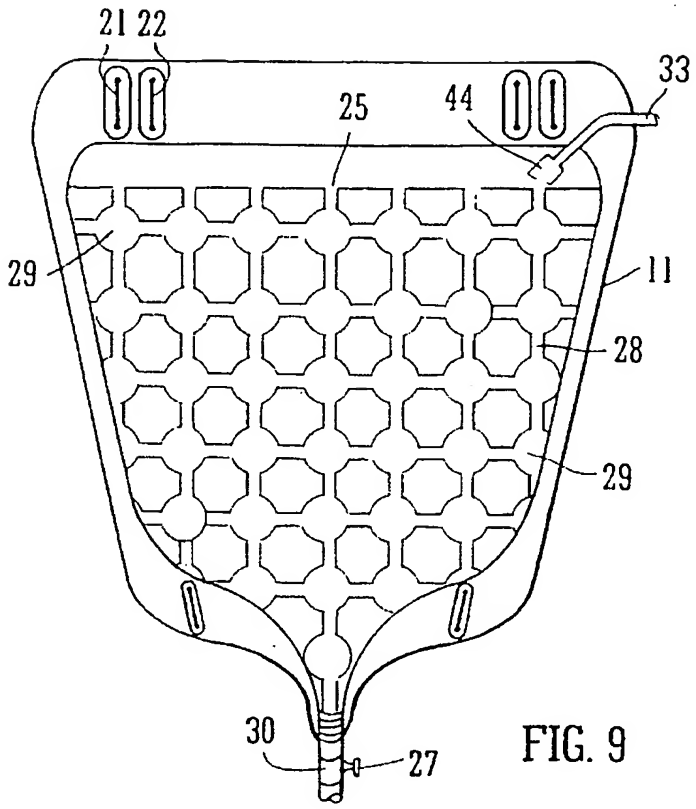

FIG. 9

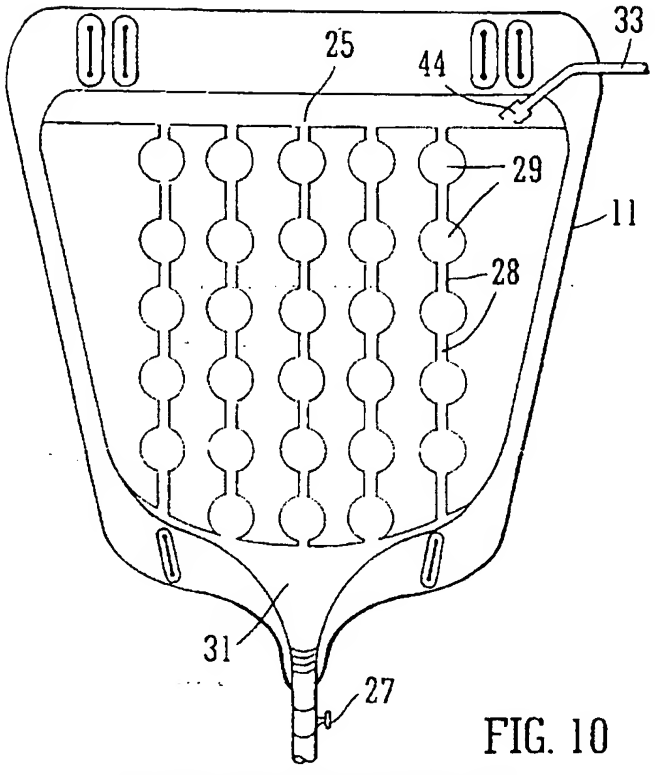

FIG. 10

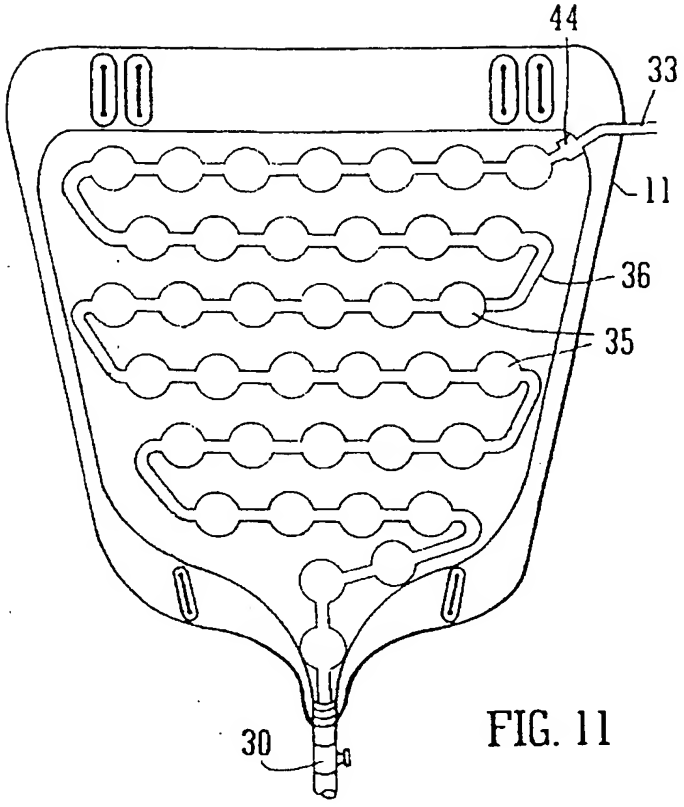

FIG. 11

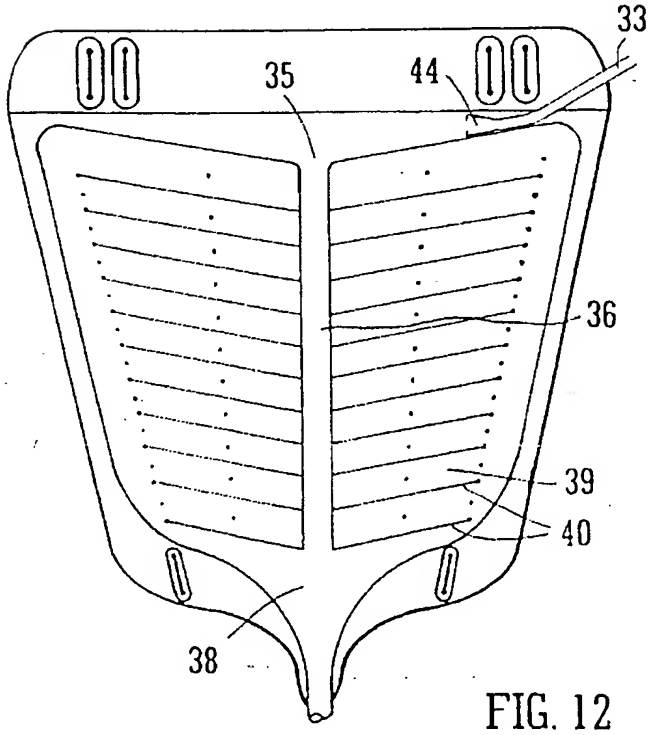

FIG. 12

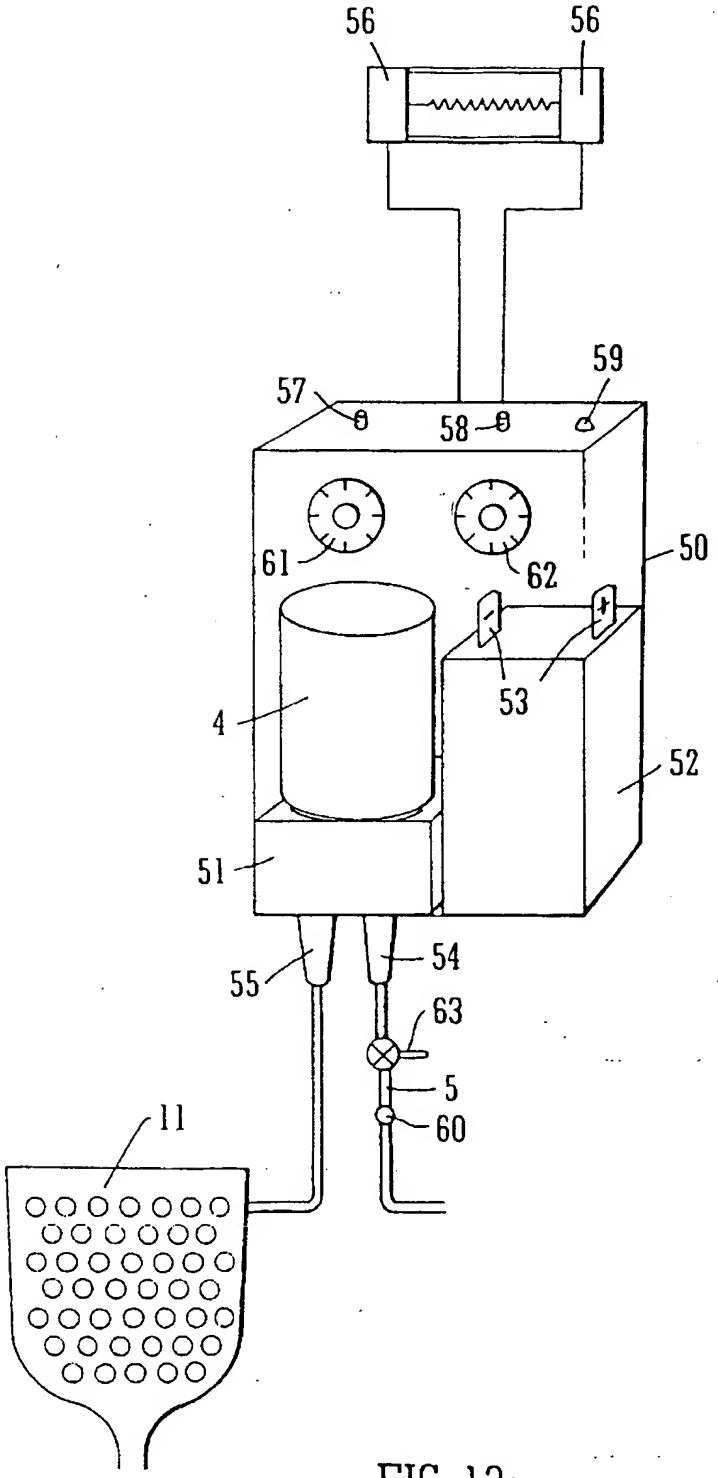

FIG. 13

INTERNATIONAL SEARCH REPORT

Internat Application No PCT/GB 99/00258

A. CLASSIFICATION OF SUBJECT MATTER

A 61 F 5/451

According to International Patent Classification (IPC) or to both national classification and IPC6

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A 61 F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	EP 0610638 A1 (A.M.C. ADVANCED MEDICAL CONCEPTS LTD.) 17 August 1994, the whole document, especially fig. 1, abstract, column 3, line 20 - column 4, line 26, column 4, line 56 - column 5, line 7, column 6, lines 25-33, column 7, lines 11, claims 1,7,11. --	1,7,8,11,18,19
A		2,6,16
Y	EP 0148047 A1	1,7-

[X] Further documents are listed in the continuation of box C.

[ ] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
22 July 1999	23. 08. 1999

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INTERNATIONAL SEARCH REPORT

Inter .al Application No
PCT/GB 99/00258

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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ANHANG

zum internationalen Recherchenbericht über die internationale Patentanmeldung Nr.

ANNEX

to the International Search Report to the International Patent Application No.

ANNEXE

au rapport de recherche international relatif à la demande de brevet international n°

PCT/GB 99/00258 BAE 223513

In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten internationalen Recherchenbericht angeführten Patentdokumente angegeben. Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The Office is in no way liable for these particulars which are given merely for the purpose of information.

La présente annexe indique les membres de la famille de brevets relatifs aux documents de brevets cités dans le rapport de recherche international visée ci-dessus. Les renseignements fournis sont donnés à titre indicatif et n'engagent pas la responsibilité de l'Office.

Im Recherchenbericht angeführtes Patentdokument Patent document cited in search report Document de brevet cité dans le rapport de recherche	Datum der Veröffentlichung Publication date Date de publication	Mitglied(er) der Patentfamilie Patent family member(s) Membre(s) de la famille de brevets	Datum der Veröffentlichung Publication date Date de publication
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